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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,009	09/26/2003	Laurent Schaller	P002022.00	7654
77218	7590	06/04/2010		
Medtronic CardioVascular Mounds View Facility South 8200 Coral Sea Street N.E. Mounds View, MN 55112			EXAMINER NGUYEN, TUAN VAN	
			ART UNIT	PAPER NUMBER
			3731	
			NOTIFICATION DATE	DELIVERY MODE
			06/04/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary

Application No.

10/672,009

Applicant(s)

SCHALLER ET AL.

Examiner

TUAN V. NGUYEN

Art Unit

3731

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19-40 is/are pending in the application.
- 4a) Of the above claim(s) 34-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S5108)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

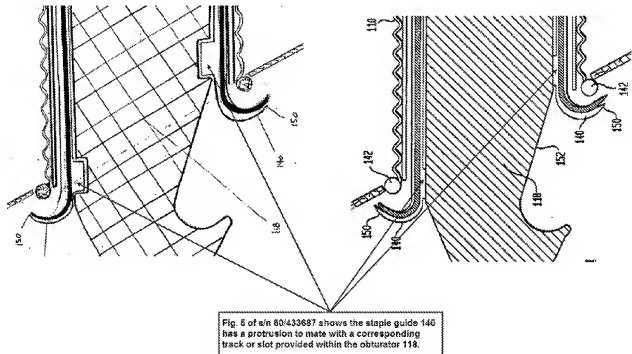
DETAILED ACTION

1. Claims 1-17 and 19-40 are pending, claims 1-17 and 19-33 are presented for examination and claims 34-40 have been withdrawn. Claims 1-17 and 19-33 were examined and rejected in previous Office action.
2. This Office action is in response to the amendment filed on 03/10/2010.

Response to Arguments

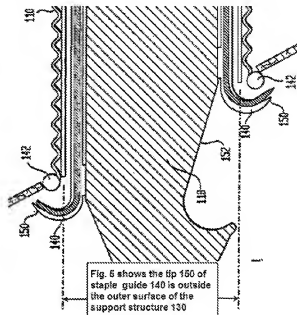
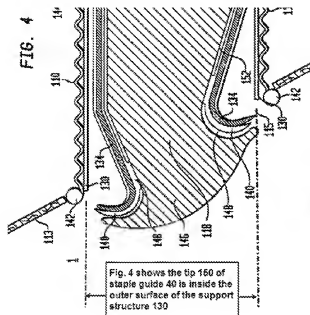
3. In page 9 of the Remark/Arguments, Applicants argue that Edoga reference (U.S. 7,335,212) do not qualify as prior art to the pending application because Figure 16 and subject matter disclosed in column 6, lines 30-40 are not disclosed in the provisional application Serial No. 60/433,687 (hereinafter Edoga '687). The argument has been fully considered but they are not persuasive. In paragraphs [0007]-[0008] of the Edoga '687, Edoga discloses "the stapler obdurator 118 includes a plurality of passages 132 extending longitudinally from the stapler obdurator 118" and "A typical stapler 100 may contain any number of such passage 132. However, it is advantageous that they contain approximately 20 passages 132....Each of the passages 132 is typically spaced with radial symmetry about the longitudinal center line 133 of the shaft 120". Figure 5 of the Edoga '687 (reproduced and annotated below this paragraph) also show each staple guide 140 includes a protrusion that is mated with a corresponding track or slot provided on the obdurator 118. In column 6, lines 35-38, of U.S. 7,335,212, Edoga discloses

Fig. 16 is the cross-section view of the device. Thus, Examiner contends that Fig. 16 and the tracks or slots 141 as shown in Fig. 16 is fully supported by the Edoga '687.



4. As to independent claim 1, Applicants argue that Edoga fails to disclose the self-closing clips are ejectable from the support structure independently of the plurality of barbs is incorrect. Figures 4-5 of Edoga's drawings show the staple guide 140 is ejected by the obturator 118 from a first position to a second position, respectively (see Figs. 4-5, reproduced and annotated below). Figure 7 shows the fastener is ejected after the staple guide 140 is in the second position (Fig. 5). Further, the wire segments 134 are movable independently of the staple guide tubes 140 because the staple guide tubes 140 is actuated by the obturator 118 and the wire segments 134 is actuated by the plunger 138. Thus, Edoga/Miller discloses the

self-closing clips are ejectable from the support structure independently of the plurality of barbs.



5. As to independent claim 31, Applicants argue that Edoga fails to disclose a first position where the distal end portion of the staple guides 140 are inside the support structure 130 to a second position where the distal end portions extend outside of the support structure is incorrect. Figure 5 of Edoga's drawings shows the barbs extended out from the outer surface of the housing filler 130 or support member. Figure 4 of Edoga's drawings shows the barbs retracted inside the outer surface of the housing filler 130 or support member (see Figs. 4-5, reproduced and annotated above).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. **Claims 31-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Edoga et al. (US 7335212).**
8. Edoga discloses (Figs. 2-7, and 16, col. 3, line 50 to col. 4, line 65 and col. 6, lines 14-40) an anastomosis device comprising: a support structure, which is the tubular structure that graft 110 is attached onto; a plurality of wire segment 134, which formed into self-closing clips 158, each clip being releasably coupled to the first plurality of members 132 and the support structure 130; a trigger 108 or a first plunger 108 movably coupled to the support structure, wherein the first plunger 108 includes plurality of pusher 138, each pusher coupled to a clip for simultaneously deployment of the clips; plurality of barbs 140 being coupled to the support structure, the barbs being separate and from the clips and each barbs slidably disposed in one second plurality of paths 141; and a second plunger 118 movably coupled to the support structure 130 and the second plunger being coupled to the proximal end of each barb 140 for simultaneously extending the

barbs between a first position where they extend from the support structure (Fig. 5) and a second position where they are retracted into the support structure (Fig. 4). Figures 4-5 of Edoga's drawings show the staple guide 140 is ejected by the obdurator 118 from a first position to a second position, respectively (see Figs. 4-5, reproduced and annotated above). Figure 7 shows the fastener is ejected after the staple guide 140 is in the second position (Fig. 5). Further, the wire segments 134 are movable independently of the staple guide tubes 140 because the staple guide tubes 140 is actuated by the obdurator 118 and the wire segments 134 is actuated by the plunger 138. Thus, Edoga discloses the clips are ejectable from the support structure independently of the plurality of barbs.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
11. **Claims 1-17 and 19-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edoga et al. (US 7335212) in view of Miller et al. (U.S. 6,709,442).**
12. Edoga discloses (Figs. 2-7, and 16, col. 3, line 50 to col. 4, line 65 and col. 6, lines 14-40) an anastomosis device comprising: a support structure, which is the tubular structure that graft 110 is attached onto; a plurality of wire segment 134, which formed into closing clips 158, each clip being releasably coupled to the first plurality of members 132 and the support structure 130 (housing filler 130); a trigger 108 or a first plunger 108 movably coupled to the support structure, wherein the first plunger 108 includes plurality of pusher 138, each pusher coupled to a clip for simultaneously deployment of the clips; plurality of barbs 140 being coupled to the support structure, the barbs being separate and from the clips and each barbs slidably disposed in one second plurality of paths 141; and a second plunger 118 movably coupled to the support structure 101 and the second plunger being coupled to the proximal end of each barb 140 for simultaneously extending the barbs between a first position where they extend from the support structure 130, with respect to the outer diameter of housing filler 130, (Fig. 5) and a second position where they are retracted into the support structure, with respect to the outer diameter of housing filler 130, (Fig. 4). Figures 4-5 of Edoga's drawings show the staple guide 140 is ejected by the obdurator 118 from a first position to a

second position, respectively (see Figs. 4-5, reproduced and annotated above).

Figure 7 shows the fastener is ejected after the staple guide 140 is in the second position (Fig. 5). Further, the wire segments 134 are movable independently of the staple guide tubes 140 because the staple guide tubes 140 is actuated by the obturator 118 and the wire segments 134 is actuated by the plunger 138. Thus, Edoga discloses the clips are ejectable from the support structure independently of the plurality of barbs.

13. Edoga discloses the invention substantially as claimed except for the clip is self-closing clip. However, Miller discloses (see Figs. 5A-5F) anastomosis device 50 comprising: a support structure and one or plurality of self-closing clip 10 slidably and disposed in tube 51, wherein the clips is shape memory clip and the clips assume a shape that automatically applies to the layers of tissue an appropriate hemostatic compression which is relatively independent of tissue thickness (see col. 3, lines 54-60). It would have been obvious to one of ordinary skill in the art to replace the clip as disclosed by Edoga with the clip as disclosed by Miller so that it too would have the same advantage.

Allowable Subject Matter

14. Claim 11 would be allowable if rewritten to include "a plurality of second plungers movably coupled to said support structure, each barb having a distal end and a proximal end, said each second plunger being coupled to each barb proximal end

so that said second plunger moves all of said barbs therewith" and to include all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **TUAN V. NGUYEN** whose telephone number is (571)272-5962. The examiner can normally be reached on 9:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
5/29/10